AIHA White Paper on Risk Assessment and Risk Management

The AIHA supports the use of human health risk assessment techniques in regulatory decision-making, the making of public health policy, and in the allocation of government and private sector resources to occupational and environmental issues. Risk assessment should be conducted with the best available scientific data. In the absence of scientific data, AIHA supports the use of health protective but reasonable default values that are selected using well-defined principles.

AIHA believes that when properly conducted, risk assessment is a valuable tool for identifying the nature and magnitude of health risks arising from a variety of sources in the workplace and the environment. Health risk assessment techniques can be effectively used to identify populations at highest risk, describe the nature of these risks and how they arise (e.g., to identify activities associated with highest risks or to indicate the dominant routes of exposure). A clearer understanding of the nature and magnitude of health risks can improve regulatory decision and policy making as well as support the appropriate allocation of government funding applied to the protection of public health and the environment.

The Environmental Protection Agency (EPA) regularly estimates the annual cost of compliance with its regulations in the billions. Recent analyses of resource allocations in the EPA ("Unfinished Business") have indicated a mismatch between these allocations and the sources of environmental and human health risk. For example, tremendous sums of money have been directed at hazardous waste site remediation, a relatively low source of risk, while minimal resources have been applied to reducing the very real risk of radon exposure. The studies blamed a variety of factors, including mandated programs, public concerns about low-risk environmental issues, and reduction of risk in some areas due to program efforts. Increasing awareness of potential misallocation of scarce resources, along with concern about high levels of uncertainty and conservative default values (i.e., assumptions used in the absence of scientific data) used in risk assessment, and instances of public frustration with risk communication efforts, have led to the passage of legislation in the United States Congress and to Executive Branch actions. The 1996 Safe Drinking Water Amendments included provisions for the integration of scientific and economic analysis as the basis for determining standards under the Act. Such integration was called for in the Office of Management and Budget implementation guidelines under Executive Order 12866.

AIHA strongly supports efforts to improve the quality of the risk assessment process by the application of the best scientific principles and data. However, the conduct of increasingly sophisticated risk assessments should not create obstacles to public health intervention. When considered prudent, preliminary or temporary precautionary risk management options should be pursued. AIHA urges improved communication of risk to the public through a more understandable and open process. AIHA believes that establishing risk assessment as the basis for rational decision making can help to better target financial and human resources to occupational health and safety and the remediation of evident environmental and human health risks. This AIHA White Paper on Risk Assessment and Risk Management delineates the AIHA position on the practice and the development of the science of risk assessment and some risk management principles.

AIHA also calls upon industry, academia and government to commit to openness of information needed for accurate risk assessment. Information about health effects studies of chemicals and processes and the means to mitigate those effects should be made readily available to workers, government agencies and the public.

AIHA position with respect to the practice of human health risk assessment:

1. AIHA believes that human health risk assessments should be conducted with the best available scientific data, and that uncertainties and known potential biases should be identified in the assessment.

AIHA recognizes that one of the biggest impediments to the use and acceptance of health risk assessments is the availability of high quality scientific data to support many of the inputs to the assessment. A key element to gaining acceptance of the use of risk assessment is the continued improvement in the sciences which are the foundation of health risk assessment and the routine disclosure of uncertainty and known potential bias.

Technical areas requiring the disclosure of uncertainty or potential bias are listed below.

Epidemiologic Assessment

- Extrapolation of results from older relatively high occupational exposures to current relatively lower occupational, non-occupational and environmental exposures.
- Evaluation of the healthy worker effect, which is a selection bias that may mask work-related health effects in studies of working populations.
- Extrapolation of results from one route of exposure to exposures via other routes.
- Extrapolation of results from so-called "negative" epidemiologic studies when the power of these studies to detect human health effects or dose-response relationships (except for very large effects) is inadequate.

Toxicity, Hazard Identification, and Dose-Response Assessment

- Extrapolation of results of animal testing to humans, including the use of scaling factors or safety factors. (When available and scientifically valid, epidemiologic data based on human exposures are preferred to toxicological data based on animal exposures.)
- Extrapolation of results of tests performed using high doses to exposures via low doses.
- Extrapolation of results of acute to chronic tests and results of subchronic to chronic tests.
- Extrapolation of results of testing performed for one route of exposure to exposures via other routes.

Exposure Assessment

- Estimates of exposure parameters such as intake rates and exposure duration and the underlying statistical assumptions.
- Use of contaminant fate and transport models to predict future exposures.

Risk Characterization

- Antagonism or synergism associated with multiple sources of exposure and multiple media exposure.
- Selection of appropriate mathematical model to calculate potential risk.

With respect to toxicity assessments, it is AIHA's position that the most scientifically appropriate data is that which most closely matches the exposure scenario being evaluated (i.e., scientifically valid epidemiologic studies of persons exposed to the same contaminants, via the same route of exposure, at a similar exposure level for the same length of time).

2. AIHA emphasizes that risk assessment is a useful analytic process that can provide valuable input into risk management. However, risk assessment often falls short of providing definitive or uncontroversial answers. It must be used with other inputs, including professional judgment, principles of public health and social and other factors.

3. AIHA supports the specification of health protective default inputs (assumption) as the only feasible approach to conducting risk assessments in the absence of scientific data. Principles for the selection of these defaults must be well defined.

Default inputs (i.e., assumptions used in the absence of scientific data) for an assessment typically arise out of both scientific and policy considerations that should be clearly stated. AIHA supports the recommendations contained in the National Research Council Report on Science and Judgment in Risk Assessment (Committee on Risk Assessment of Hazardous Air Pollutants, 1994), which identifies criteria to be considered in formulating such principles, including:

- Protecting public health;
- Ensuring scientific validity;
- Minimizing serious errors in estimating risk;
- Maximizing incentives for research; and
- Creating an orderly and predictable process for fostering openness and trustworthiness.

- Most important is the use of scientific information in selection of default options.

4. AIHA supports the use of an iterative approach to the assessment process in which relatively simple techniques are used initially to identify the potential magnitude of the health risk, followed by more sophisticated analyses as needed. The conduct of increasingly sophisticated analysis should not preclude public health intervention where warranted.

The appropriate use of resources for characterizing health risks requires that an iterative approach to risk assessment be applied, beginning with techniques that are relatively simple, inexpensive, and sometimes highly uncertain or conservatively biased (i.e., tend to overstate actual risk). The uncertainties and biases incorporated in such assessments need to be clearly described. If such screening assessments show a clear danger to health, immediate protective action should be taken. If such screening assessments support the conclusion of no significant risks, further evaluation is unwarranted. However, means should be developed to ensure that chemicals are re-evaluated when new information and data indicate that a previously un-recognized risk may exist. If screening assessments suggest unacceptable risks, though they may still be due to uncertainty or bias, further resources can be invested in increasingly sophisticated and expensive techniques to provide a more rigorous scientific basis for decision-making.

The conduct of increasingly sophisticated risk assessments should not be used to create an obstacle to public health intervention. When considered prudent, preliminary or temporary risk management options should be pursued (e.g. the replacement of chemicals with safer alternatives, cleanup contamination, engineering controls to reduce exposure to a safe level for workers). When such temporary risk management options are pursued, a plan and timeline should be developed for the implementation of permanent corrective actions, with full consultation of affected parties.

The iterative approach to risk assessment involves the initial use of simple techniques, progressing to more complex analyses. Examples of assessment techniques, starting with simpler methods and progressing to more complex, are listed below.

Toxicity, Hazard Identification, and Dose-Response Assessment

- Non-biological, mathematical dose-response models (e.g., a linearized multistage model);
- Physiologically based, pharmacokinetic (PB-PK) models; and
- Tissue-response mechanistic models.

Exposure Assessment

- Using conservative point estimates of exposure parameters in screening assessments
- Specification of exposure parameters in terms of probability distributions; and
- Exposure monitoring when feasible.
- Presentation of uncertainty should be appropriate to the degree of sophistication of the risk analysis.

5. AIHA supports the calculation and presentation of risk assessment results that include an assessment of uncertainty with a narrative describing the rationale and assumptions used. Quantitative uncertainty assessment in terms of probability distributions (i.e., central tendency, with upper and lower limits) or qualitative characterization of uncertainty should be presented, depending on the type and complexity of the risk assessment, and the data available. Single point estimates with no characterization of uncertainty are unacceptable. Deterministic ?bright-line? estimates imply absolute certainty where none exists and hide the true nature and level of our ignorance relative to the technical opinion of the danger.

AIHA supports the use of probability distributions derived from measured data or statistical methods in the calculation and presentation of risk estimates as a basis for rational decision-making. When communicated to the public with clear statements of assumptions and procedures, a qualitative or quantitative assessment of uncertainties can make the risk assessment process more understandable and accessible. Scientific uncertainty about the predictors of risk (i.e., toxicity assessment and exposure assessment) has two sources: the natural variability of these predictors, and lack of knowledge about them. By fully characterizing the calculated risk and the underlying uncertainty associated

with the estimates, knowledge that the assessment is based on sound study data or that significant gaps in data information exist will be communicated to those making decisions and to stakeholders.

The evaluation of uncertainty should be tailored to the type and complexity of the risk assessment, such that simple techniques are used initially and advanced techniques are used for more sophisticated risk assessments. There are many methods for evaluating uncertainty, including those listed below.

- Quantitatively describing the basis used for selecting default values, exposure estimates, etc.
- Using sensitivity analysis to determine which predictor variables contribute the most to the uncertainty or variability of the predictions.
- Providing an analytical uncertainty propagation that examines how uncertainty in individual parameters affects the overall uncertainty of the assessment.
- Developing a probabilistic uncertainty analysis in which the overall distribution of uncertainty is developed based on the individual distributions for the values of relevant parameters.
- Using classical statistical methods to estimate uncertainty where measured data exists.
- Setting aside a concealed subset of data in order to evaluate the estimates calculated from the remaining data.

Whichever method is selected, it must be communicated to the public with clear statements of the assumptions and procedures used.

6. AIHA supports, as an essential component of the total risk assessment process, the adoption of a performance-oriented generic exposure standard to protect all workers from workplace exposure to biological, chemical and physical hazards. Details may be found in the AIHA White Paper entitled "A Generic Exposure Assessment Standard," amended and adopted on May 18, 1997. Exposure issues continue to be the area that most involve industrial hygienists in the risk assessment process.

7. AIHA believes that exposure data for both the workplace and other environments are often collected without sufficient ancillary information or data elements to use the data effectively for exposure assessment purposes. Because uncertainty in exposure assessments is often a significant contributor to the uncertainty of risk assessments, the AIHA therefore favors efforts to substantially improve the collection of appropriate data elements with exposure measurements. Details of specific recommendations for workplace data can be found in the joint recommendations of the ACGIH and AIHA (Appl.Occup.Environ.Hyg. 11(11). November, 1996).

8. AIHA understands and endorses the concept that quantitative risk assessment requires a quantitative estimate of risk per unit exposure at all exposure levels of interest. Thus, exposure limits should be presented with the quantitative level of (or range of) residual risk extant at the specific exposure limit, based on conceptual and mathematical models of the dose-response.

9. AIHA believes that the risk assessment process should be open, and that presentation of results should be understandable, to all stakeholders, including those with alternative hypotheses and conclusions.

AIHA acknowledges there is considerable debate in the scientific community regarding the practice of risk assessment, and believes the resulting scientific disputes should be stated clearly and openly in risk assessments. The outcome of a risk assessment (i.e., the estimate of occurrence of additional illness or injury), can sometimes vary by orders of magnitude, depending on the underlying assumptions of any given risk assessment. Although these assumptions should be based strictly on scientific considerations, in reality they are influenced by value judgments. The participation of all stakeholders should be ensured by establishment of a defined mechanism for submission and consideration of alternative hypotheses and conclusions. Such participation, along with clear explanations in risk communications of the assumptions, choice of models, uncertainties, and limitations of the analysis, will make the process more open and understandable, and ensure that the perspectives of all stakeholders are taken into consideration. The selection of risk management alternatives, which have the potential to strongly impact the public, is subject to a variety of inputs, including social, cultural, economic, religious, spiritual, moral, and political concerns. AIHA strongly supports efforts to obtain the input of all stakeholders in the selection of acceptable risk management alternatives. AIHA also regards the guidelines for stakeholder involvement as described in The Commission's Final Report (Volume 1) as appropriate in determining the nature and extent of such involvement.

AIHA agrees with the call of the National Academy of Science/National Research Council Report, in Science and Judgment in Risk Assessment, for an open, structured, and documented risk assessment process, with identification of uncertainties, and a clear link between risk characterization and research needs.

10. AIHA endorses the concept that risk assessment should be comprehensive and accountable to all involved parties in its approach and should include all of the potentially exposed populations (including sensitive persons) or ecosystems.

Essential components of any risk assessment are that they must be based on the best available scientific data, reasonable and justifiable assumptions and models, and must be clearly written so that others can understand the assessment, including assumptions made, default values used, uncertainties, etc. Risk assessments should be comprehensive, to encompass the substances of concern, likely substitutes, and all potentially exposed persons (including sensitive populations) or ecosystems. Comprehensiveness is critical in ensuring the risk management decision made is based on an informed understanding of all aspects of the risk assessment. Decisions based on risk assessments which do not encompass all aspects of the exposed populations or ecosystems may result in unacceptable risks to populations or ecosystems not addressed and potential disproportionate economic burdens for certain industrial or commercial segments.

Risk assessment should explicitly examine the impact of the hazard on the most sensitive workers, communities, and ecosystems. The most vulnerable populations should be used for the model. However, care should be taken to ensure that sensitive subpopulations are not "double-counted" by the concurrent use of overly conservative toxicity and exposure values.)

11. AIHA supports the use of risk comparisons in risk analysis and communication only when the calculated risks being compared have similar characteristics.

Risk comparison is a tool frequently used in risk communication to equate unfamiliar risks with those that are more familiar (e.g., the risk of living near a chemical plant as compared to the risk of exposure to radon). AIHA believes that such comparisons are appropriate only when the characteristics or dimensions of the risks are similar. An involuntary, man-made catastrophic risk should not be compared with one that is voluntary, natural, and chronic in nature. AIHA believes that the context in which a risk occurs can be as important as the magnitude of the risk.

AIHA supports the Commission's recommendation that comparative risk-ranking paradigms are appropriate for setting priorities for environment, health and safety standards and for ultimately guiding regulatory agency, resource-allocation decisions.

AIHA encourages the following to support the development of the practice of human health risk assessment:

12. AIHA encourages increased financial support for activities which contribute to the development and refinement of epidemiology, toxicology, and exposure science to reduce the uncertainty and bias in health risk assessment, thereby increasing its utility for regulatory decision making, the making of public health policy, and in the allocation of governmental resources.

The major obstacle in the conduct of risk assessment studies is the limited knowledge base in epidemiology, toxicology, and exposure science. Ideally, risk assessment should be a straightforward evaluation of the health or environmental effects in relationship to exposure, integrated over time. The reality is that uncertainty in toxicity values and exposure parameters frequently results in selection of conservative default values and assumptions, which in turn may lead to overestimation of risk. Uncertainty and the judgments that are forced on the risk assessor as a result of this lack of essential knowledge can and will severely limit the usefulness, objectivity, and ultimately the credibility of the process.

AIHA, therefore, supports the development of databases and models for epidemiology, toxicology, and exposure assessment, which will allow for the application of a more quantitative approach to risk evaluation, particularly in the practice of industrial hygiene. The data and models currently available in the published literature are generally only suitable for screening-level evaluations, in which conservative estimates are useful in making statements such as "risk is not higher than this value." However, these screening level evaluations are usually very uncertain and generally do not support more targeted decisions for risk reduction for specific subpopulations, work activities, etc. To improve the targeting of risk reduction measures, it is crucial that professionals gathering and developing epidemiology, toxicology, and exposure assessment data collect and document all relevant data, and that this data

be made available in the published literature. Further, many of the currently available exposure models are based on theoretical approaches, which have not been fully validated. In some cases, the underlying assumptions and model limitations are not well documented; therefore these models may be misused and resulting estimates may be misinterpreted. Validation of current and future models is essential to ensure the models are indeed providing reasonable, justifiable estimates of exposure that are useful in making risk reduction decisions.

To further the utility of risk assessment to environmental issues having the potential to cause the greatest harm to the public, while allocating scarce governmental resources efficiently, financial support of science in the following areas is critical to the further development of health risk assessment:

- Development of publicly available epidemiologic, toxicological, and exposure databases.
- Development of well-documented and validated exposure models.

AIHA further urges that research initiatives include both public and private ventures. A re-evaluation of the regulatory requirements for the risk assessment process provides an opportunity to encourage cooperation of the public and private sectors, with the potential for creating the best science. Such collaboration may be synergistic, increasing the quantity and quality of research findings beyond that which could be achieved by each sector alone.

13. AIHA supports the appointment of expert advisory panels (including stakeholders, regulatory authorities, and representatives from labor, industry, academia, and professional/technical organizations) to assist in the development of risk assessment guidelines and criteria. These guidelines will be used to identify and highlight key areas requiring further research and regulation.

AIHA believes that empowerment of expert panels will allow the development of risk assessment guidelines and criteria that reflect current scientific thinking, and which can be revised in response to new findings in epidemiology, toxicology, and exposure science. Specific guidelines, criteria, and standards which are mandated by legislation or regulation become very difficult to revise (e.g., the Occupational Safety and Health Administration's Permissible Exposure Limits have changed very little since 1971). In contrast, the Threshold Limit Values, which were the original basis for the Permissible Exposure Limits, have been revised frequently and thus reflect recent scientific opinions. The fluidity of the Threshold Limit Values is due to the nature of the process, which allows the TLV Committee of the American Conference of Governmental Industrial Hygienists to propose revisions as deemed necessary. The discipline of risk assessment is highly subject to change, as scientific and technological developments continue to advance the supporting disciplines of epidemiology, toxicology, exposure assessment, and risk characterization. The appointment of expert advisory panels would allow persons who are recognized experts in the methods and conduct of risk assessment and in the supporting disciplines to contribute to the development of state-of-the-art risk assessment guidelines and criteria which could be revised as needed. Inclusion of stakeholders on the panels will contribute to the openness of the process, and ensure the consideration of the varying perspectives of all parties. Advisory panels should meet periodically to review guidelines and criteria for consistency with current scientific thinking.

AIHA recommends that an expert advisory panel be convened to identify and recommend action on key areas in occupational and environmental risk assessment requiring further research and regulation. Stakeholders, regulatory authorities, labor, industry, academia, and professional/technical organizations should be represented on the panel, which should be convened at least once every five years.

AIHA believes that all regulatory agencies involved in performance of risk assessments and management should strive for intra-agency and inter-agency consistency and predictability.

14. AIHA endorses the findings and recommendations of the Presidential/Congressional Commission on Risk Assessment and Risk Management presented in its final report (volume 1 and 2) published in 1997.

The Commission developed an integrated, systematic, comprehensive Risk Management Framework that is a forward-looking strategy addressing multiple environmental media and multiple sources of risk. The framework has six stages:

1. Identify and characterize the **problem** and put in **its public health and ecological context**.

2. **Analyze** the risks associated with the problem in context based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.

3. **Examine** a range of regulatory and non-regulatory options for addressing the risks.

4. Make **decisions** about which options to implement based on the best available scientific, economic and other technical information.

5. Take **effective, expeditious and flexible** actions to implement the decisions.

6. Conduct an **evaluation** of the results of the actions.

The framework is conducted in **collaboration** with stakeholders and using iteration if new information is developed that changes the need for or nature of risk management.

AIHA also endorses other Commission recommendations:

- That a common metric for comparing health risks be developed by environmental protection and public health agencies by evaluating two approaches: the EPA's margin-of-exposure and the more universally used safety factor approach.
- That decision criteria used in setting and evaluating compliance with standards, tolerances, cleanup levels or other regulatory actions (i.e. bright lines for risk management) be established by the regulatory agencies and not Congress.
- That regulatory agencies should explore alternative regulatory approaches to decision-making such as negotiated rulemaking, alternative dispute resolution techniques and expert peer reviews.
- That risk characterizations intended for risk managers and the public should include narrative descriptions of the primary reasons for uncertainty and variability. They should include specific weight of the evidence conclusions about exposure, toxicity and susceptibility. AIHA recognizes that the Commission has recommended against "the routine use of formal quantitative analysis of uncertainties in the evaluation of toxicity in risk estimation". AIHA believes however, that quantitative expressions of uncertainty are needed to qualify point estimates

of toxicity and risk and should be used alongside narrative descriptions of uncertainty.

15. AIHA believes that OSHA needs to assess and improve its regulatory effectiveness in several areas:

- Congress should direct OSHA and NIOSH to improve their cooperation and to increase efforts to quantifying risks, costs and benefits. This will help OSHA to assess how regulations can be improved to increase workplace health and safety and to guide its setting of regulatory priorities.
- OSHA should publish guidelines that lay out its scientific and policy defaults and explain and justify its actions when it evaluates or regulates a substance differently from other federal agencies that regulate the same substance.
- OSHA should update its existing Permissible Exposure Limits (PELs) and develop new PELs for air contaminants.

16. The AIHA is well aware that this decade will require continuing and dedicated work on toxicology, exposure assessment, risk assessment, risk management, and risk communication. The primary issues that will be addressed include improvement of

- Toxicological information regarding the relevance of animal results to humans;
- The science of exposure assessment so that we will have the necessary tools to objectively evaluate (or at least reasonable screen) the majority of exposure scenarios in the workplace and the nonoccupational settings;
- Communication of relative risk to all individuals, scientists, regulators and the general public;
- Educational methods and materials for toxicology, exposure assessment, risk assessment, risk management and risk communication, especially those geared towards educating workers, the public and

others without training in those areas and which may help to prepare persons to serve on stakeholder panels; and,

- Scientific methods to associate exposure information, especially inhalation and/or ingestion of air contaminants and skin contact with surface contamination, to various agents with actual dose and dose-response information.

These emerging issues will open up substantial opportunities for specialists who are uniquely qualified to evaluate potential hazards, exposures, and risks to chemicals and to take appropriate actions to effectively and efficiently manage and communicate these risks to workers, the general public, consumers, communities, and the government.

References:

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